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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,992	03/02/2004	Mikhail Nemenov		1316

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EXAMINER

JOHNSON III, HENRY M

ART UNIT PAPER NUMBER

3739

DATE MAILED: 08/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/790,992	Applicant(s) NEMENOV ET AL.	
	Examiner Henry M. Johnson, III	Art Unit 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 October 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "14" has been used to designate both a camera (in specification) and PC (Fig. 1). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "20" and "26" have both been used to designate controller. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

The delivery fiber is labeled "29" in the figures, yet is cited as "24" in the specification.

Specification

35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms, which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

On page 2, the word "include" should be including.

On page 3, the word "the" should be inserted before spinal cord.

On page 4, the phrase "rapidly become to quiescent" does not read correctly.

On page 35, the first paragraph doe not read properly.

On page 35, "the set of command" is unclear.

Claim Objections

Claim 1 is objected to because of the following informalities: the wording "said pulses to infrared" is not proper. Appropriate correction is required.

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 4-25 have been renumbered 2-23.

Claim Rejections - 35 USC § 112

Claims rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 10 recites the limitation "the temperature sensor" in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 is indefinite as the controller does not provide laser pulses, but controls the pulses of a laser.

Claims 13-23 are indefinite for a process claim claiming dependency of a system claim.

Claims 22 and 23 are indefinite as it is not clear how single mode stimulation would be achieved, as the levels for C-fiber nociceptors are higher than for Aδ-fiber nociceptors.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 5-8 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 6,267,779 to Gerdes. Gerdes teaches an apparatus for delivery of infrared energy to a target, the preferred wavelength of the infrared lasers is between approximately 900 nm and approximately 1100 nm with the best results being obtained with a wavelength of about 980 nanometers (Col. 5, lines 25-27). The infrared energy is delivered to a treatment wand via optical fiber and is further collimated using a lens prior to delivery to the treatment site (Col. 8,

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lines 25-35). The apparatus further includes a controller, a control panel, a power source, and components configured to vary the radiation power and energy, pulse frequency, pulse duration, and duration of the biostimulation treatment (Col. 6, lines 58-62). The controller is disclosed as a single board computer, which is interpreted as a personal computer. The absorption coefficient is dependent on wavelength and the wavelength of Gerdes inherently meets the absorption limitation.

Regarding claims 5-7, the limitations are based on intended use with no impact on the device structure. A recitation with respect to the manner in which an apparatus is intended to be employed does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim. In re Pearson, 494 F.2d 1399, 181 USPQ 641 (CCPA 1974); In re Yanush, 477 F.2d 958, 177 USPQ 705 (CCPA 1973); In re Finsterwalder, 436 F.2d 1028, 168 USPQ 530 (CCPA 1971); In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 136 USPQ 458 (CCPA 1963); Ex parte Masham, 2 USPQ2d 1647 (BdPatApp & Inter 1987).

Claims 12-17 are rejected under 35 U.S.C. 102(a) as being anticipated by Inward currents in primary nociceptive neurons of the rat and pain sensations in humans elicited by infrared diode laser pulses"; Greffrath et al.; International Association for the Study of Pain, September 2002. Greffrath et al. Greffrath et al. teaches that stimulation of the human skin with radiant heat stimuli generated by infrared lasers typically leads to a stinging and/or burning sensation. This painful sensation is mediated through activation of peripheral endings of A δ - and C-fiber nociceptors. A personal computer controlled laser platform based on six GaInAs/GaAs laser diodes (980 nm wavelength) yielding up to 15 W output power into a flexible glass fiber core is disclosed for thermal stimulation. Stimulus intensity was changed by varying

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the laser power (2.8–11 W) and/or stimulus duration (4–400 ms). The interstimulus interval following the appearance of I_{heat} was at least 44 s.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,267,779 to Gerdes. as applied to claim 1 above, and further in view of U.S. Patent 5,540,676 to Freiberg. Gerdes is discussed above, but does not teach using an optical fiber less than 100 micrometers in diameter. Freiberg teaches the use of optical fiber for the delivery of laser surgical energy that may be in the infrared range (Col. 2, lines 19) and the fiber is disclosed as having a diameter as small as 85 micrometers (Col. 2, line 30). It would have been obvious to one skilled in the art to use the 85 micrometer fiber as taught by Freiberg in the invention of Gerdes as a skilled artisan would select the size fiber best suited to the instant application to provide the required energy levels and spot size.

Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 6,267,779 to Gerdes as applied to claim 1 above, and further in view of U.S. Patent 6,210,882 to Landers et al. Gerdes is discussed above, but does not teach closed loop temperature control. Landers et al. discloses an apparatus and method for controlling the temperature of a target area (sample) using an infrared source that may be a diode laser (Col. 13, line 67). Feedback from a temperature sensor is provided to a computer for controlling the energy source (Col. 15, lines 10-20). It would have been obvious to one skilled in the art to use the closed loop temperature control as taught by Landers et al. in the invention of Gerdes to control the temperature of the target area as such control is old and well known having been pervasively used in numerous arts.

Claims 18-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greffrath et al. as applied to claim 12 above, and further in view of U.S. Patent 6,210,882 to Landers et al. Greffrath et al. are discussed above, but do not teach closed loop temperature control. Landers et al. discloses an apparatus and method for controlling the temperature of a target area (sample) using an infrared source that may be a diode laser (Col. 13, line 67). Feedback from a temperature sensor is provided to a computer for controlling the energy source (Col. 15, lines 10-20). It would have been obvious to one skilled in the art to use the closed loop temperature control as taught by Landers et al. in the method of Greffrath et al. to control the temperature of the target area as such control is old and well known having been pervasively used in numerous arts.

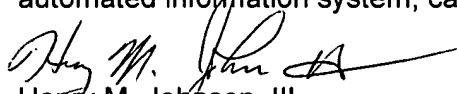
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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Henry M. Johnson, III whose telephone number is (571) 272-4768. The examiner can normally be reached on Monday through Friday from 6:00 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Henry M. Johnson, III
Primary Examiner
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